REMARKS

This is in response to a non-final office action dated November 1, 2007 (the "Office Action"), in which Claims 22-41 and 59-66 were pending. In the Office Action, Examiner Szmal: (1) objected to the drawings under 37 CFR 1.84(p)(4) because reference character 150 has been used to designate both an analog-digital converter and a blood vessel; (2) objected to claim 66 because "the balloon" in line 2 of the claim lacks antecedent basis; (3) objected to Claims 31-34 and 66 as being dependent upon a rejected base claim; (4) rejected Claims 22-24, 29, 30, 35, 36, and 59-65 under 35 U.S.C. § 103(a) as being unpatentable over European Patent Publication No. EP1025805A1 to Krivitski ("the '805 Krivitski") in view of U.S. Patent No. 5,453,576 to Krivitski ("the '576 Krivitski"); (5) rejected Claim 25 under 35 U.S.C. § 103(a) as being unpatentable over '805 Krivitski in view of '576 Krivitski and in further view of U.S. Patent No. 5,665,103 to Lafontaine et al. ("Lafontaine"); (6) rejected Claims 26-28 under 35 U.S.C. § 103(a) as being unpatentable over '805 Krivitski in view of '576 Krivitski and in further view of U.S. Patent No. U.S. Publ. No. 2004/0254495 A1 to Mabary et al. ("Mabary"); (7) rejected Claims 37-39 under 35 U.S.C. § 103(a) as being unpatentable over '805 Krivitski in view of '576 Krivitski and in further view of U.S. Publ. No. 2002/0049488 A1 to Boneau ("Boneau"); and (8) rejected Claims 40-41 under 35 U.S.C. § 103(a) as being unpatentable over '805 Krivitski in view of '576 Krivitski and in further view of U.S. Patent No. 6,471,656 to Shalman et al. ("Shalman").

In response to the Office Action, Applicant addresses each of these rejections and objections. Reconsideration of the rejections and objections, as well as allowance of the pending

claims, are respectfully requested in light of the present amendments and comments below.

I. The Drawings Are Not Objectionable Under 37 C.F.R. 1.84(p)(4).

The Examiner objected to the drawings under 37 C.F.R. 1.84(p)(4) because reference character 150 had been used to designate both an analog-digital converter and a blood vessel. In response, Applicant respectfully submits the enclosed replacement drawing sheet, which is in compliance with 37 C.F.R. 1.121(d). As shown on the replacement drawing sheet, Figure 3 has been amended so that the analog-digital converter corresponds to reference character 153 (rather than reference character 150). Further, the specification has been amended to refer to "analog-to-digital converters 153" rather than "analog-to-digital converters 150."

In addition, Figure 3 has been amended so that the computer corresponds to reference character 157 (rather than reference character 160, which also referred to the stent in Figure 7). Further, the specification has been amended to refer to "PC module 157" and "computer 157," rather than "PC module 160" and "computer 160," respectively.

Applicant respectfully submits that the objection to the drawings under 37 C.F.R. 1.84(p)(4) should be withdrawn in light of the replacement sheet submitted herewith.

II. The Objection To Claims 31-34 Should Be Withdrawn.

The Examiner objected to Claims 31-34 as being dependent upon a rejected base claim, noting that the claims would be allowable if they were rewritten in independent form including all of the limitations of the base claim and any intervening claims. In response, Applicant thanks

the Examiner for his determination of allowable subject matter. Further, Applicant amends Claim 31, as suggested by the Examiner, to include all of the limitations of Claim 22, from which Claim 31 previously depended. Consequently, amended Claim 31 is allowable because it is in independent form and no longer depends from a rejected base claim.

Similarly, Claims 32-34 are allowable because each depends from allowable Claim 31. *See* MPEP § 2143.03 ("If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious." (citing *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988))).

Therefore, Applicant respectfully submits that the objection to Claims 31-34 should be withdrawn and the claims allowed.

III. The Objections To Claim 66 Should Be Withdrawn.

The Examiner objected to Claim 66 for two reasons: (1) "the balloon" term lacked antecedent basis and (2) the claim depended from a rejected base claim. The Examiner noted, however, that the claim would be allowable if it were rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In response, Applicant thanks the Examiner for his determination of allowable subject matter. Further, Applicant amends Claim 66, as suggested by the Examiner, to include all of the limitations of Claims 22 and 39, from which Claim 66 previously depended. In addition, Claim 66 has been amended to include the step of "inflating with a fluid a balloon attached to the catheter," which provides proper antecedent basis for the "the balloon" claim term and the "the fluid" claim term in Claim 66.

Consequently, Applicant respectfully submits that amended Claim 66 is allowable because it is in independent form, no longer depends from a rejected base claim, and includes proper antecedent basis for the "the balloon" claim term. Applicant respectfully requests that the objections to Claim 66 be withdrawn.

IV. Claims 22-24, 29, 30, 35, 36, And 59-65 Are Allowable Over '805 Krivitski And '576 Krivitski.

The Examiner rejected Claims 22-24, 29, 30, 35, 36, and 59-65 under 35 U.S.C. § 103(a) as being unpatentable over '805 Krivitski in view of '576 Krivitski. The Examiner alleged that '805 Krivitski discloses each limitation of each of the claims, except that it fails to disclose (1) that the first and second solutions differ with respect to the conductivities of the solutions (as claimed in Claims 22-24, 29, 30, 35, 36, and 59-65) and (2) that the first and second solutions are heated to body temperature or a common temperature prior to injection (as claimed in Claims 63-64). The Examiner also alleged that '576 Krivitski discloses the missing limitations, and that it

> would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Krivitski ('805) to include the use of two different NaCl solutions, as per the teachings of Krivitski ('576), since it would provide a means comparing the conductivity measurements between the two solutions in order to obtain a more accurate cross-sectional measurement.

(Office Action, at 4.) The Examiner further argued that "[i]t also would have been obvious to one or ordinary skill in the art to utilize an equal volume of the first and second solutions since it would provide a standard measure of the two solutions while only differing in conductivity." (*Id.* at 4-5.)

Applicant respectfully submits that the Examiner has failed to set forth a *prima facie* case of obviousness under § 103(a). According to the Manual of Patent Examining Procedure, "[t]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness." MPEP § 2142 (8th ed., rev. 6). "If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness." *Id.* Therefore, the rejection should be withdrawn for the following reasons.

A. The Cited References Do Not Disclose All Of The Claimed Limitations.

Neither '805 Krivitski nor '576 Krivitski, alone or in combination, discloses the invention claimed in Claim 22. For example, neither reference discloses the step of "calculating the cross-sectional area of the treatment site based on the first and second conductance values and the conductivities of the first and second solutions," as claimed in amended Claim 22.

The '805 Krivitski discloses performing a single-injection method to determine a blood flow (or cross-sectional area), performing a second single-injection method to determine a second blood flow, then merely comparing the two blood flows to determine whether there has been any change in blood flow over the period of time between the two injections. (*See* '805 Krivitski, ¶¶ 0059-62; *see also id.* ¶¶ 0012-13.) Not only does this method use two injections only to determine a change in flow over time, each of its single-injection measurements provides only an average blood flow (and therefore an average cross-sectional area) calculated over time, as evidenced by the '805 Krivitski method's reliance on integrals and areas under the curve. (*See, e.g.*, '805 Krivitski, ¶¶ 0046, 0049, 0052; fig. 7.)

Similarly, the '576 Krivitski reference uses two injections having different conductivities for calibration purposes (*see* '576 Krivitski, col. 14, ll. 45 – col. 15, l. 9) and for determining the change in impedance values over time (*see id.*, col. 1, ll. 53-59, col. 15, l. 26 – col. 16, l. 36, col. 16, l. 52 – col. 17, l. 30).

By contrast, the claimed method calculates an instantaneous cross-sectional area, rather than an average cross-sectional area or the change in cross-sectional area over time, based on the first and second conductance values and the conductivities of the first and second solutions. (*See* Application, claim 22; *id.*, pg. 13, ll. 14-16 ("The values of CSA(t) and $G_p(t)$ can be determined at end-diastole or end-systole (i.e., the minimum and maximum values) or the mean thereof."); *see also id.*, pg. 12, l. 26 – pg. 13, l. 21.) The average cross-sectional area can be determined from the instantaneous cross-sectional area, but the instantaneous cross-sectional area cannot be determined from an average cross-sectional area.

The ability to determine an instantaneous cross-sectional area is important because it permits physicians to obtain an accurate, immediate measurement of the cross-sectional area of a blood vessel during a medical procedure, such as the placement of a stent. (*See* Application, pg. 5, ll. 22-31; *id.*, pg. 7, l. 22 – pg. 8, l. 9.) Furthermore, analysis of instantaneous cross-sectional area values – but not of average cross-sectional area values – provides the pulsatility of the vessel, which gives an indication of the compliance or stiffness of the vessel as a measure of the extent of disease. (*See id.*, pg. 17, ll. 12-19 ("When the CSA, pressure, wall thickness, and flow data are determined according to the embodiments outlined above, it is possible to compute the compliance (e.g., $\Delta CSA/\Delta P$), tension . . . , stress . . . , strain . . . , and wall shear stress . . . .

These quantities can be used in assessing the mechanical characteristics of the system in health and disease.").)

Therefore, Applicant respectfully requests that the rejections based on the Krivitski references be withdrawn.

B. The Examiner's Reasoning For Combining The Krivitski References Is Improperly Conclusory.

"The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." MPEP § 2142. Indeed, "[t]he Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." *Id.* (emphasis added). Moreover, the "Federal Circuit has stated that 'rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *Id.* (internal citation omitted).

Applicant respectfully submits that the Examiner has not offered an explicit analysis to support the obviousness rejection. Instead, the rejection is based on mere conclusory statements. For example, the Examiner stated that the two Krivitski references should be combined because "it would provide a means comparing the conductivity measurements between the two solutions in order to obtain a more accurate cross-sectional measurement." (Office Action, at 4.) However, the Examiner has not provided any reasoning to explain why one of ordinary skill in the art would have expected that the use of two solutions with different conductivities (as disclosed in the '576 Krivitski reference), when combined with the '805 Krivitski method, would

have made the resulting cross-sectional area determinations more accurate. In addition, nothing in either '805 Krivitski or '576 Krivitski indicates that using two different solutions having two different conductivities would allow for a comparison of conductivities that would enable "a more accurate cross-sectional measurement." As discussed below, such a combination would not be pursued by a person of ordinary skill in the art because the combination of teachings would actually tend to decrease the accuracy of the average cross-sectional area measurements obtained through the '805 Krivitski method. (*See infra.*)

Thus, Applicant respectfully submits that the Examiner's conclusory reasoning does not provide any support for the obviousness rejection, and the Examiner failed to provide an explicit analysis on which his conclusions properly could be based. Consequently, Applicant respectfully requests that the rejection be withdrawn.

C. The Two Krivitski References Cannot Be Combined Without Rendering the '805 Krivitski Method Unsatisfactory For Its Intended Purpose.

"If [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification," and the *prima facie* case of obviousness cannot be established. MPEP § 2143.01 (8th ed., rev. 6). In this case, the Examiner's proposed modification of the '805 Krivitski method renders the method unsatisfactory for its intended purpose for two reasons, and the obviousness rejection should therefore be withdrawn.

First, '576 Krivitski's use of two different solutions with two different conductivities, discussed in the passage cited by the Examiner, would not be properly used with the '805 Krivitski method because the combination would introduce inconsistency into the '805 Krivitski

method (and therefore potential error into the results obtained therefrom). As discussed above, the '805 Krivitski method relies on a comparison of two single-injection blood flow measurements. ('805 Krivitski, ¶¶ 0012, 0059-62, 0067.) The purpose of the '805 Krivitski method's use of two cross-sectional measurements is to compare the results of the two measurements (*i.e.*, a pre-medical procedure measurement vs. a post-medical procedure measurement) to determine whether the intervening medical procedure improved blood flow. (*See id.* ¶¶ 0001, 0007-09, 0012.) In other words, the first single-injection blood flow measurement provides a baseline blood flow value to which the second blood flow value (obtained from the second single-injection measurement) is compared. Thus, to obtain the most accurate comparison, the techniques and methods of measurement should be standardized (*i.e.*, consistent between the first and second measurements). Consistency between the two measurements is important so that any difference in the measured values is actually a result of the intervening medical procedure, rather than the result of an altered measuring procedure. In other words, all measurement parameters should remain the same so that any difference in the blood flow values between the two measurements can be considered to be caused by the medical treatment.

However, using two different solutions having two different conductivities would introduce an inconsistency between the first and second measurement procedures. Rather than increasing the accuracy of the blood flow determinations, such an inconsistency could cause a fluctuation between the first and second blood flow measurements that would not be attributable to the intervening medical procedure. Thus, the combination of the teachings of the two

references would potentially decrease the accuracy of the blood flow comparison of the '805 Krivitski method, rendering the method unsatisfactory for its intended purpose.

Second, the teachings of '576 Krivitski cited by the Examiner would render the method of '805 Krivitski inoperable. The cited portion of the '576 Krivitski reference suggests using one isotonic saline solution and one hypertonic saline solution for determining the impedance of the lung fluid. ('576 Krivitski, col. 16, l. 52 – col. 17, l. 5.) However, using an isotonic saline solution as an indicator in the method of '805 Krivitski would likely prevent the impedance sensor (blood property sensor 40) from detecting the presence of the saline solution. "The blood property sensor 40 is selected to identify a change in a parameter of the blood." ('805 Krivitski, ¶ 0034; *see id.*, ¶ 0046, fig. 7.) If the sensor 40 is designed to detect changes in impedance, but the addition of the saline solution does not result in a significant change in impedance (because the saline solution is isotonic to the blood), then the sensor will not function properly to accurately determine the blood flow or cross-sectional area. (*See* '805 Krivitski, ¶¶ 0046, 0052, 0059, fig. 7; *cf.* '576 Krivitski, col. 3, ll. 13-16 ("[I]ndicators having a different . . . electrical impedance than that of the bloodstream may be used, with appropriate sensors, to detect changes in blood characteristics.").) Consequently, the '805 Krivitski method would not work for its intended purpose.

D. There Was No Reasonable Expectation of Success In Combining The References.

"The prior art can be modified or combined to reject claims as *prima facie* obvious [only if] there [was] a reasonable expectation of success" at the time the invention was made. MPEP § 2143.02 (8th ed., rev. 6). In this case, a person of ordinary skill in the art would not have had a

reasonable expectation that using two different solutions with different conductivities in the method of '805 Krivitski would have been successful.

As explained above, the '805 Krivitski method is used to compare two blood flow (or cross-sectional area) measurements to determine whether a medical procedure occurring between the two measurements improved the blood flow. (*See* '805 Krivitski, ¶¶ 0001, 0007-09, 0012.) Thus, one of ordinary skill in the art would understand that maintaining consistency between the methods used to take the two measurements (*i.e.*, standardizing the methods) would produce the most accurate results of the comparison between the measurements. The '576 Krivitski's suggestion to use a different solution with a different conductivity for the second measurement is contrary to the goal of method standardization, and there was therefore no expectation of success in combining the references (and no reasons for doing so).

In addition, there was no expectation of success because the '805 Krivitski method uses a sensor that detects changes in a blood parameter and the '576 Krivitski reference teaches using an isotonic saline solution indicator. Where the blood parameter to be measured is impedance, one of ordinary skill in the art would not have expected that the use of an isotonic indicator would be significantly detectable to the sensor such that the method would function properly. *See supra.*

Thus, for all of the reasons discussed herein, there was no reasonable expectation of success in combining the teachings of the two Krivitski references, and Applicant respectfully submits that no *prima facie* case of obviousness has been established.

E. Claims 23-24, 29, 30, 35, 36, and 59-65 Are Allowable Because They Depend From Allowable Claim 22.

Each of Claims 23-24, 29, 30, 35, 36, and 59-65 depend, directly or indirectly, from Claim 22. Because Claim 22 is allowable, as discussed above, each of these dependent claims is also allowable over the combination of the Krivitski references (alone or in further combination with any of the other cited references). *See* MPEP § 2143.03 ("If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious." (citing *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988))).

V. The Remaining Claims Are Allowable Because They Depend From An Allowable Independent Claim.

Applicant respectfully requests that the Examiner withdraw the remaining obviousness rejections to Claim 25, Claims 26-28, Claims 37-39, and Claims 40 and 41. Each of these claims depends (directly or indirectly) from Claim 22, which is shown above to be allowable over the combination of the Krivitski references. Therefore, each of Claims 25-28 and 37-41 is allowable over the combination of the Krivitski references (alone or in combination with any other of the cited references). *See* MPEP § 2143.03 ("If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious." (citing *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988))).

VI. The Amendments To The Claims And The Specification Do Not Add New Matter.

Neither the claim amendments nor the amendments to the specification introduce new matter into the Application.

The amendment to Claim 22 corrects an error in the claim by specifying that the conductivities are of the "first and second solutions" rather than the "first and second compounds." This was an obvious error and the clarification is amply supported by the specification as originally filed. (*See, e.g.*, Application, pg. 7, l. 29 – pg. 8, l. 1; pg. 12, l. 26 – pg. 13, l. 7; pg. 14, ll. 22-26; pg. 19, ll. 17-18.) This change was also incorporated into the amendments to Claims 31 and 66, each of which was amended to incorporate the limitations of Claim 22.

As explained above, the amendments to Claim 31 merely incorporate the limitations of Claim 22, as suggested by the Examiner. Similarly, the amendments to Claims 66 incorporate the limitations of Claims 22 and 39, as suggested, and provide for proper antecedent basis of certain claim terms. These amendments do not introduce any new matter.

Also, as explained above, the amendments to the Specification and to Figure 3 correct the use of certain reference numerals, but do not add new matter.

Accordingly, Applicant respectfully requests that the amendments to the claims and the specification, as well as the new drawing sheet, be accepted and entered.

VII. Interview Request.

If the Examiner determines that there are any further objections or rejections that would prevent this Application from proceeding to allowance, the Examiner is invited to contact the undersigned to arrange an interview with the undersigned to discuss such objections or rejections.

CONCLUSION

For all the foregoing reasons, it is respectfully submitted that Applicant has made a patentable contribution to the art and that this response places the above-identified application in condition for allowance. Favorable reconsideration and allowance of this application is respectfully requested. If any issues remain, the Examiner is encouraged to contact the undersigned at the number listed below.

It is believed that no additional fees are owed. In the event Applicant has inadvertently overlooked the need for an extension of time or payment of an additional fee, Applicant conditionally petitions therefor, and authorizes any fee deficiency to be charged to deposit account 09-0007. Please reference our number P01568-US-01 (25518.0010) when making such a charge.

Respectfully submitted,

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